

**ROUTING SLIP**  
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**DATE OF CORRESPONDENCE:** 12/12/01

**DATE INTO FDA:** 01/07/02

**TO:** BERNARD A SCHWETZ HF-1

**FROM:** SUSAN VICKERS, CATHOLIC HEALTHCARE WEST

**SYNOPSIS:** COMMENTS ON 99P-2077, SUPPORTS HEALTH CARE WITHOUT HARMS PETITION  
ON DEVICES THAT MAY LEACH PHTHALATE PLASCICIZERS

**LEAD OFFICE:** HFA-305

**HOME OFFICE:** HF-40

**CONTACT/PHONE#:** MIKELE A BRYANT 301-827-4450

**COPIES:** HFZ-1

**COORDINATION:**

**SIGNATURE REQUIRED:**

**REFERRALS FROM HF-40**

| <b>ASSIGNED TO</b> | <b>ACTION</b>             | <b>DUE DATE</b> |
|--------------------|---------------------------|-----------------|
| -----<br>HFA-305   | -----<br>NECESSARY ACTION | -----           |
| HFZ-1              | NECESSARY ACTION          |                 |



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December 12, 2001

Bernard Schwetz, DVM, PhD, Acting Commissioner  
Food and Drug Administration  
5600 Fishers Lane, Room 14-71  
Rockville MD 20857

Dear Dr. Schwetz:

Catholic Healthcare West supports the Health Care Without Harm (HCWH) petition to the United States Food and Drug Administration (FDA), filed on October 4, 2001. This petition for reconsideration asks the FDA grant, in part, HCWH's 1999 petition to:

1. Develop a regulation or guideline to label medical devices that leach phthalate plasticizers
2. Establish a program to promote alternatives.

In its September 5, 2001 **Safety Assessment of Di (2-ethylhexyl) phthalate (DEHP) Released from PVC Medical Devices**, the FDA warned that some medical products made from polyvinyl chloride (PVC) may expose patients to unsafe amounts of the plasticizer (DEHP). The FDA concluded that exposures to patients during the following medical procedures may exceed the tolerable intake of DEHP:

- Adults and infants undergoing extracorporeal membrane oxygenation (ECMO) therapy;
- Infants undergoing exchange transfusions;
- All patients receiving enteral nutrition; infants receiving total parenteral nutrition (TPN);
- Adults undergoing cardiopulmonary bypass; and
- Nursing infants of mothers on hemodialysis.

While the FDA document does not attempt to quantitatively assess the risk posed by exposure of patients to DEHP, it does note that aggregate exposures to DEHP from multiple devices can result in doses that exceed the tolerable intake. For example, the FDA calculates that infants receiving multiple treatments in neonatal intensive care units may be receiving 20 times more DEHP from medical device related sources than what the agency considers tolerable. The safety assessment also describes aggregate exposures for adult patients undergoing ECMO and coronary artery bypass procedures.

Given the FDA's findings in its safety assessment, we support Health Care Without Harm's request that the FDA:

- Take formal action to implement responsive action, including identifying the agency's commitments including timelines, benchmarks, medical devices and areas of utilization targeted, etc.;
- Initiate rulemaking or issue a guidance consistently requiring labeling of:
  - a. All PVC medical devices that, according to the FDA Safety Assessment, may under some circumstances leach DEHP at levels approaching or in excess of

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tolerable intake including those used to administer Total Parenteral Nutrition with added lipids to infants; to transfuse blood during trauma, ECMO or in exchange transfusion to neonates; during cardiopulmonary bypass or to provide enteral nutrition;

- b. All PVC medical devices that may pose, when used by pregnant or potentially pregnant women, prenatal exposures to DEHP at any level;
  - c. All PVC medical devices that may be utilized in conjunction with Breast Pumps and Breast Milk and leach DEHP into the breast milk;
  - d. All PVC medical devices that may contribute to levels of DEHP in the milk of breast feeding women where the Safety Assessment indicates that the levels of DEHP may approach or exceed the Tolerable Intake (TI) of the breast feeding infant;
  - e. All PVC medical devices that may leach DEHP when used intentionally or inadvertently with lipid-containing nutrition or lipophilic drugs;
  - f. All PVC medical devices that may leach DEHP that could add to the DEHP exposure of patients that are also undergoing a medical procedure that, according to the FDA Safety Assessment, may under some circumstances leach DEHP at levels approaching or in excess of tolerable intake; and
  - g. All medical devices that may cause non-systemic effects as indicated in Annex D of the FDA Safety Assessment of DEHP medical devices.
- Develop a market information and education program that informs health care providers of the potential hazards of DEHP and the availability of alternatives that either are DEHP-free, or are not capable of leaching DEHP. Our health care system would welcome the opportunity to be involved in preparation of a risk communication strategy.
  - Maintain an up-to-date inventory on the FDA website and in written agency publications, such as *FDA Consumer*, of the medical devices on the market that leach plasticizers and any FDA-approved non-DEHP and non-PVC alternatives known to be available as substitutes.

Finally, let me note my understanding that both the California Medical Association and the American Medical Association have passed resolutions addressing the impact of DEHP leaching and urging proper product labeling and education of healthcare providers.

Thank you for your attention to this important and urgent matter.

Sincerely,



Susan Vickers

Director of Advocacy